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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,743	06/30/2004	Rohit Ravikant Soni	Sun Pharma	4641
22925	7590	05/25/2006	EXAMINER	
PHARMACEUTICAL PATENT ATTORNEYS, LLC 55 MADISON AVENUE 4TH FLOOR MORRISTOWN, NJ 07960-7397			CHUNG, SUSANNAH LEE	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/501,743	SONI ET AL.	
	Examiner	Art Unit	
	Susannah Chung	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 32-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 32-52 are currently pending in the instant application and are subject to the following new lack of unity requirement. Claims 1-31 have been canceled by preliminary amendment filed on 30 June 2004.

Lack of Unity Requirement

Restriction is required under 35 U.S.C. 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 32-52 are drawn to more than one inventive concept (as defined in PCT Rule 13), and accordingly, restriction is required according to the provision of PCT Rule 13.2. PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a general inventive concept (requirement of unity of invention). PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(b), provides that “special technical features” mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1(e), provides combinations of different categories of claims and states:

“The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

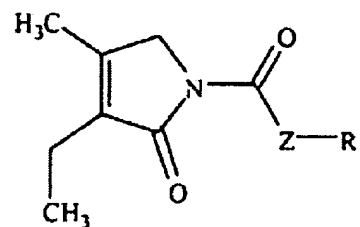
(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or

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(iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specifically designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted. Due to the numerous and widely



divergent variables of the intermediate compound of formula (3),

wherein

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Z is O, S or NY, wherein Y is C₁-C₅-alkyl, C₁-C₅-haloalkyl, aryl or aralkyl, and

R is aryl or heteroaryl, where aryl or heteroaryl radical is unsubstituted or substituted by one or more radicals from the group consisting of nitro, halogen, cyano, azido, haloalkyl, CO-R¹, SR², SO-R³ and SO₂-R⁴,

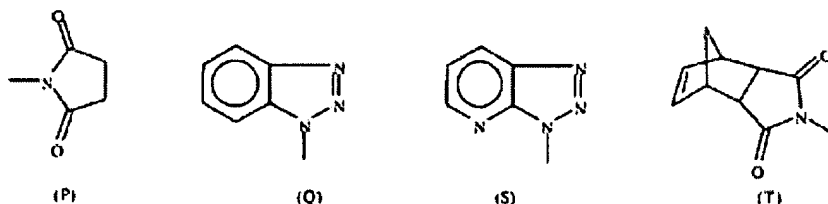
R¹ is H, C₁-C₅-alkyl, C₂-C₅-alkenyl, C₂-C₅-alkynyl, C₁-C₅-alkoxy or C₂-C₅-alkenoxy,

R² is C₁-C₅-alkyl, C₂-C₅-alkenyl, C₂-C₅-alkynyl, C₁-C₅-haloalkyl or C₂-C₅-haloalkenyl,

R³ is C₁-C₅-alkyl, C₂-C₅-alkenyl, C₂-C₅-alkynyl, C₁-C₅-haloalkyl or C₂-C₅-haloalkenyl,

R⁴ is C₁-C₅-alkyl, C₂-C₅-alkenyl, C₂-C₅-alkynyl, C₁-C₅-haloalkyl or C₂-C₅-haloalkenyl, or

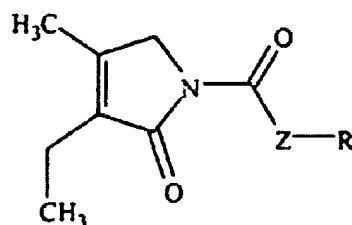
the moiety represented below by P, Q, S or T.



a precise listing of inventive groups cannot be made. The following groups are exemplary:

Z is oxygen:

Group I: Claims 48-52 drawn to the intermediate compound of formula (3),



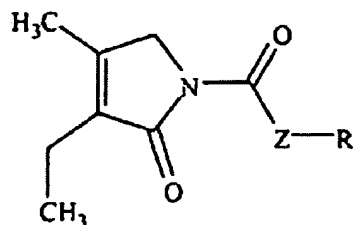
, wherein Z is O and R is phenyl and claim 33 drawn to the process

of preparation of the compound of formula (3), comprising reacting a compound of formula (2),

wherein Z is O and R is phenyl.

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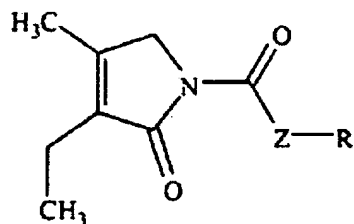
Group II: Claims 48-52 drawn to the intermediate compound of formula (3),



, wherein Z is O and R is phenyl and claim 37-47 drawn to the process of preparation of the compound of formula (3), wherein Z is O and R is phenyl.

Z is sulfur:

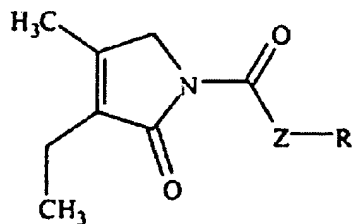
Group III: Claims 48-52 drawn to the intermediate compound of formula (3),



, wherein Z is S and R is phenyl and claim 33 drawn to the process of preparation of the compound of formula (3), comprising reacting a compound of formula (2), wherein Z is S and R is phenyl.

Z is nitrogen:

Group IV: Claims 48-52 drawn to the intermediate compound of formula (3),

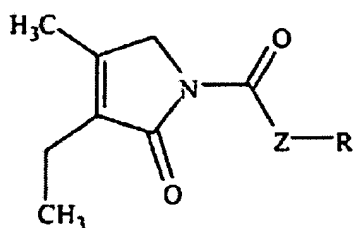


, wherein Z is N-Y, wherein Y is aralkyl (CH₂-CH₂-phenyl) and R is SO₂NH₂ and claims 32 and 34-36 drawn to the process of preparation of the compound of

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formula (4), comprising reacting a compound of formula (3) with 4-(2-aminoethyl)benzene sulfonamide to obtain 4-[2-(3-ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide.

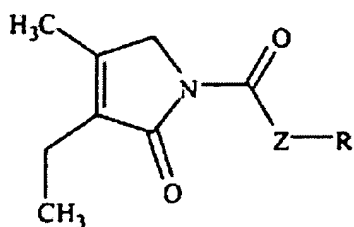
Group V: Claims 48-52 drawn to the intermediate compound of formula (3),



, wherein Z is N-Y, wherein Y is methyl and R is phenyl and claim

33 drawn to the process of preparation of the compound of formula (3), comprising reacting a compound of formula (2), wherein Z is N-Y, wherein Y is methyl and R is phenyl.

Group VI: Claims 48-52 drawn to the intermediate compound of formula (3),



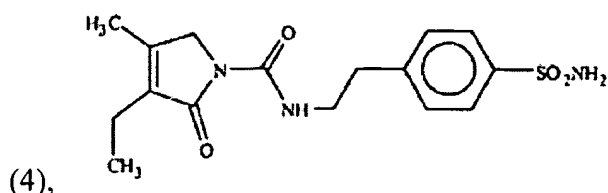
, wherein Z is N-Y, wherein Y is phenyl and R is phenyl and claim

33 drawn to the process of preparation of the compound of formula (3), comprising reacting a compound of formula (2), wherein Z is N-Y, wherein Y is phenyl and R is phenyl.

The inventions listed as Groups I through VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: they do not share the same essential structural element(s) that define the “special technical feature” necessary to specify a contribution over the prior art.

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The structural moiety common to Groups I and II is the compound of formula (3), wherein Z is oxygen; the structural moiety common to Group III is the compound of formula (3), wherein Z is sulfur; and the structural moiety common to Groups IV through VI is the compound of formula (3), wherein Z is nitrogen. A preliminary search based on the compound of formula



, wherein Z is N-Y, wherein Y is CH₂-CH₂-

phenyl and R is SO₂NH₂, is known in the art (see U.S. Pat. Num. 4,379,785; CAS RN 119018-29-0, N-[2-[4-(aminosulfonyl)phenyl]ethyl]-3-ethyl-2,5-dihydro-4-methyl-2-oxo-1H-pyrrole-1-carboxamide) and therefore, cannot be said the special technical feature, which makes a contribution over the prior art. All other substituents differ structurally from one another. In addition, the various process claims all require different reactants and/or reagents and/or reaction conditions and/or products. Thus, these claims lack the corresponding special technical feature(s) necessary to link them together to fulfill the lack of unity invention requirement.

Therefore since the claims are drawn to more than a product and more than a process, the claims lack unity of invention and should be limited to only a product of the formula (3), for example wherein Z is N-Y and R is phenyl and its process for preparation.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Again, this list is not exhaustive as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention (a product and a process of making that product) by identifying another

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specific embodiment, i.e. another value for Z, R, etc..., not listed in the exemplary groups of the invention and examiner will endeavor to group the same.

A telephone call was made to Attorney Mark Pohl on 05/11/2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Telephone Inquiry

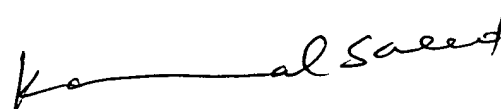
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098.

The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susannah Chung
Patent Examiner, AU 1626
Date: 16 May 2006


KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER